UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	
v.	**Criminal No: 09-CR-10330-GAO**
(1) STRYKER BIOTECH, LLC, **(2) MARK PHILIP,** **(3) WILLIAM HEPPNER,** **(4) DAVID ARD and** **(5) JEFFREY WHITAKER,**	**MOTION TO DISMISS**
Defendants.	

DEFENDANT STRYKER BIOTECH, LLC'S
MOTION TO DISMISS COUNT 13

Count 13 charges that Defendant Stryker Biotech "knowingly and willfully" made a "materially false statement" to the FDA, in violation of 18 U.S.C. § 1001(a)(2). As the Government's recent submissions to the Court have made clear, Count 13's charge is based on the legally invalid theory of "collective intent." Accordingly, in addition to granting defendants' previously filed motions to sever, this Court should dismiss Count 13.[1] *See* Fed. R. Crim. P. 12(b)(2).

I. FACTUAL AND PROCEDURAL BACKGROUND

OP-1 Putty is a Humanitarian Use Device ("HUD") that the FDA-approved in April 2004 under a Humanitarian Device Exemption ("HDE"). As part of OP-1 Putty's HDE approval,

[1] The oft-criticized "collective intent" theory seeks to impute to a corporation a *mens rea* that not a single one of its agents or employees individually possessed. *See, e.g., United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010) (rejecting the government's theory that a company can "knowingly" file a false claim even where no "particular [company] employee knew that the company's claims were false"); *Commonwealth v. Life Care Ctrs. of Am., Inc.*, 456 Mass. 826, 833 (Mass. 2010) ("[T]he Commonwealth seeks to satisfy its burden to prove wanton or reckless conduct on the part of the corporate defendant by adding together the actions and omissions of corporate employees who at worst have been merely negligent. Such aggregation is not supported by logic or law.").

Stryker Biotech was required to submit a regulatory report to the FDA at the end of April each year. On April 30, 2007, Stryker Biotech's Assistant Director of Regulatory Affairs, Donna Supko, signed and submitted to the FDA a cover letter attaching Stryker Biotech's 2007 Annual Report. The report, which itself was unsigned, was 52 pages long with an additional 52 pages of appendices The first page of the report listed Bernadette Alford, Stryker Biotech's then-Vice President of Regulatory Affairs, as the company's "Authorized Representative." The report did not mention the names of any other Stryker Biotech employee.

Among other things, the report stated that 6,234 units of OP-1 Putty had been sold between April 2006 and March 2007 inclusive. The report further stated that, "'[s]ince 2 units of OP-1 Putty are used per patient, it is estimated that 3,117 patients [had] been treated'" with the device during that twelve-month period.[2] Count 13 of the Superseding Indictment charges that, by including that latter statement in the 2007 Annual Report, "**STRYKER BIOTECH, LLC** . . . knowingly and willfully made a materially false statement and representation" to the FDA because "**STRYKER BIOTECH, LLC** knew that less than 2 units [of the device] were used per patient and that more than 4,000 patients had been treated during" that twelve-month period.[3]

[2] The FDA-approved package insert for OP-1 Putty directs the surgeon to use one unit of OP-1 on each side of the spine (*i.e.*, two units per patient).

[3] Perhaps to demonstrate the materiality of this supposed misrepresentation, the Superseding Indictment alleges that Stryker Biotech "could only lawfully sell approximately 5,200 units" of OP-1 Putty per year. . . ." Superseding Indictment, at ¶ 50; *see also id.* at ¶ 49 (alleging that Stryker Biotech "could only sell approximately 5,200 units of OP-1 Putty per year (4,000 patients x 1.3 units/patient = 5,200 units)"). That allegation is baseless. Neither the Food, Drug, and Cosmetic Act nor the FDA's implementing regulations contain any such numerical restriction on sales. To the extent the Government asserts otherwise, it is misreading the applicable statutory provisions. *See* 21 U.S.C. § 360j(m)(2) (providing that a device is eligible for HDE approval if, *inter alia*, it is "designed to treat . . . a disease or condition that affects fewer than 4,000 individuals in the United States"). Indeed, in April 2008, Stryker Biotech voluntarily informed the FDA that, based on a reassessment of historical sales invoices, it was likely that more than 4,000 patients had been treated with OP-1 Putty during both the 2007 and 2008 reporting periods. The FDA did not assert that this level of sales constituted some sort of legal violation or somehow compromised OP-1 Putty's statutory eligibility for continued HDE approval.

The Superseding Indictment does not allege that any particular agent or employee of Stryker Biotech "knowingly and willfully" made the allegedly false statement contained in the 2007 Annual Report, nor did the Government provide the grand jury with evidence supporting such an allegation. *Cf. United States v. Newell*, 658 F.3d 1, 38-39 (vacating a false statement conviction because, although the evidence "clearly established" that the defendant "signed the 269 form, and that the 269 form misrepresented" certain material facts, "the evidence as to whether [the defendant] knew that the information he was filing was materially incorrect . . . [was] skimpy"). The Government has recently, and generically, asserted that Defendant Mark Philip, Stryker Biotech's former President, was "closely involved in" and "approved" or "authorized" the filing of the 2007 Annual Report, *see* Gov't Opp., Dkt. #163, Ex. A at 7, 8 (Nov. 7, 2011). But the Superseding Indictment does not allege that Philip actually reviewed the report before it was filed or otherwise knew that the report contained a false statement regarding the number of patients treated with OP-1 Putty, nor did the Government present the grand jury with evidence supporting such an allegation. Finally, the Government has never claimed that the individual members of the Stryker Biotech Regulatory Affairs department who prepared, reviewed, and submitted the 2007 Annual Report either were participants in the separately charged conspiracy to defraud doctors into mixing Calstrux with OP-1 (the unindicted co-conspirators that the Government has identified were all sales personnel), or committed any other criminal violations for that matter.

The Government, however, does not believe any of this to be fatal to Count 13. As the Government recently made clear, Count 13 is based on a theory of "collective intent" that, in the Government's view, would allow the jury to convict Stryker Biotech merely upon proof that the 2007 Annual Report contained an inaccurate estimate of the number of patients treated with OP-1 Putty. In other words, the Government believes that it can convict the corporate defendant

Stryker Biotech on Count 13 even if none of its agents or employees could be convicted for knowingly and willfully making a false statement in connection with this 2007 Annual Report.

II. ARGUMENT

To convict a defendant under 18 U.S.C. § 1001(a)(2), a jury must find beyond a reasonable doubt not merely that the defendant made a false statement, but also that the defendant made that false statement "*willfully*." *See United States v. Gonsalves*, 435 F.3d 64, 72 (1st Cir. 2006) (holding that, to establish the "willfulness" element, the government must prove that the defendant "knew that his statement was false when he made it or . . . consciously disregarded or averted his eyes from its likely falsity"). This "*mens rea* [element] is a vital component of a section 1001 violation." *United States v. Curran*, 20 F.3d 560, 567 (3d Cir. 1994). The Government's argument in this case is that a jury would be entitled to convict Stryker Biotech on Count 13 even though not a single person working at Stryker Biotech is alleged to have "willfully" made the allegedly false statement contained in the 2007 Annual Report. The Government is wrong as a matter of law.

A. The Government's "Collective Intent" Theory Is Legally Invalid.

Although the First Circuit has yet to address the validity of the "collective intent" theory on which Count 13 clearly is based, several other Courts of Appeals have roundly rejected it. For example, in *United States v. Science Applications International Corporation*, the D.C. Circuit held that the district court legally erred when it instructed the jury that it could find SAIC liable of violating the False Claims Act, "if it determined that 'at least one individual employee of SAIC had actual knowledge of an organizational conflict of interest that contradicted . . . statements and claims that [SAIC] made and presented to the [Nuclear Regulatory Commission].'" 626 F.3d 1257, 1273 (D.C. Cir. 2010) (vacating the jury's verdict due to the instructional error). The D.C. Circuit explained that, although the False Claims Act's "scienter

element" does not require "proof of specific intent, . . . 'collective knowledge' [nevertheless] provides in an inappropriate basis for proof of scienter." *Id.* at 1274. Because the civil False Claims Act's scienter element ("knowingly") is essentially equivalent to, and certainly not more demanding than, the *mens rea* element for a felony false statement charge ("willfully") as the First Circuit defined it in *Gonsalves*, the result and reasoning in *Science Applications* compels the rejection of the Government's "collective intent" theory in this case.

The Government might argue that *Science Applications* is inconsistent with the First Circuit's decision in *United States v. Bank of New England*, 821 F.2d 844 (1st Cir. 1987). This Court can reject that argument out of hand. As the D.C. Circuit explained in *Science Applications* itself, "although the First Circuit in *Bank of New England* allowed the jury to infer corporate knowledge of facts through the accumulation of individual [employees'] knowledge, proof of the proscribed intent in that case depended on the wrongful intent of *specific* employees." *Sci. Applications*, 626 F.3d at 1275 (disagreeing with the government's argument that *Bank of New England* endorsed a "collective intent" theory). Indeed, in *Bank of New England*, the district court had instructed the jury that, to "'find that the bank [ ] willfully failed to file'" currency transaction reports, in violation of 31 U.S.C. § 5322, the jury had to find "'either than *an employee* within the scope of his employment willfully failed to file a required report or that the bank was flagrantly indifferent to its [reporting] obligations.'" 821 F.2d at 855 (quoting the district court's jury instruction on willfulness). The First Circuit found "no error" in this "willfulness" instruction. *Id.* And in holding that the evidence was sufficient to prove "willfulness" — the very same *mens rea* element that applies to Count 13 — the First Circuit did not rely on any sort of "collective intent" concept. Instead, the court pointed out that **(1)** "head [bank] teller Patricia Murphy knew that McDonough's transactions were reported but, on one occasion, deliberately chose not to file a CTR on him because he was 'a good customer,'" and

(2) because the evidence showed that specific employees both "regarded McDonough's transactions as unusual . . . and suspected that he was structuring his transactions to avoid [the currency transaction] reporting requirements" with which they were familiar, the jury "could have concluded that the failure by [these] Bank personnel to, at least, inquire about the reportability of McDonough's transactions constituted flagrant indifference to the obligations imposed by the Act." *Id.* Thus, *Bank of New England* offers no support to the Government's theory that Count 13's "willfulness" element can be satisfied through a "collective intent" theory.

In addition to the D.C. Circuit, numerous other Courts of Appeals have rejected the "collective intent" theory on which the Government is proceeding here. In *Chaney v. Dreyfus Service Corporation*, the Fifth Circuit held that "where 'an essentially subjective state of mind is an element of a cause of action,' we have declined to allow this element to be met by a corporation's collective knowledge, instead requiring that state of mind 'actually exist' in at least one individual [agent or employee]." 595 F.3d 219 (5th Cir. 2010) (quoting *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 366 (5th Cir. 2004)). Similarly, in *Teamsters Local 445 Freight Division Pension Fund v. Dynex Capital, Inc.*, the Second Circuit held that "[t]o prove liability against a corporation, of course, a plaintiff must prove that an agent of the corporation committed a culpable act with the requisite scienter." 531 F.3d 190, 195 (2d Cir. 2008). In *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, the Seventh Circuit refused to adopt a "collective intent" theory that would "attribute to a corporation a state of mind that none of its employees had." 513 F.3d 702, 707-08 (7th Cir. 2008).

Although *Chaney*, *Dynex*, and *Tellabs* were civil cases, this is a distinction without a difference. Indeed, as a matter of logic, using "collective intent" as a basis to impose *felony criminal liability* on a corporation would be even more inappropriate than using it as a basis to impose civil liability. As the Massachusetts Supreme Judicial Court held just last year, using a

"collective intent" theory as a means to impose felony criminal liability on a corporation "not only is illogical but also raises due process concerns" because of the "stigma and other serious consequences" that a criminal conviction "would impose on [the] corporation." *Commonwealth v. Life Care Ctrs. Of Am., Inc.*, 456 Mass. 826, 834-35 (2010) ("[T]he majority of Federal courts to consider the issue have reached the conclusion that, in both the criminal and civil contexts, a corporation acts with a given mental state only if at least one employee who acts (or fails to act) possesses the requisite mental state at the time of the act (or failure to act)."); *see also United States v. LBS Bank-New York, Inc.*, 757 F. Supp. 496, 501 n.7 (E.D. Pa. 1990) ("Although knowledge possessed by employees is aggregated so that a corporate defendant is considered to have acquired the collective knowledge of its employees, specific intent cannot be aggregated similarly. Thus, in order for the verdict against LBS to stand, there must be evidence from which a jury could reasonable determine that at least one agent of LBS had the specific intent to join the conspiracy to defraud the government.").

Stryker Biotech is not aware of any case supporting the use of the "collective intent" theory as a basis for imposing felony criminal liability on a corporation under Section 1001. Particularly in light of the strong trend in the case law *against* the use of the "collective intent" theory, there is no basis for the Court to break new legal ground. This Court should therefore hold that the Government's "collective intent" theory is legally invalid.

B. The Government's Generic Assertions Regarding Mark Philip's Role in "Stryker Biotech's Annual Reports Process" Cannot Save Count 13 From Dismissal.

In opposing defendants' motions to sever, the Government vaguely asserted that, at trial, it expects to show that Mark Philip **(1)** "was closely involved in Stryker Biotech's annual reports process, and approved the annual reports," Gov't Surreply, Dkt. #163, Ex. A at 7 (Nov. 7, 2011),

and **(2)** "knew that the relevant numbers in the April 2007 report were false and authorized the April 2007 annual report's submission to the FDA," *id.* at 8.

The Government's vague assertions amount to nothing more than a claim that, had Mark Philip personally reviewed the 2007 Annual Report, he would have recognized that the report's statement regarding the number of patients treated with OP-1 Putty was inconsistent with "internal company studies," performed in February 2005, that he "knew of."[4] Even if the Government were to argue that Philip could have — or even *should have* — personally reviewed the 2007 Annual Report before he "approved" or "authorized" its submission, this would not constitute a valid argument that Philip "knowingly and willfully" made a false statement to the FDA. *Cf. United States v. Robison*, 505 F.3d 1208, 1229 (11th Cir. 2009) ("At most, the government proved that Robison negligently submitted documents to the EPA, but that is insufficient [to sustain a Section 1001 conviction].").[5]

[4] The "internal company studies" to which the Government refers were the various analyses performed by a member of the company's marketing department in or around February 2005. The Superseding Indictment alleges that those analyses purported to show that, at that time, Stryker Biotech was not selling an average of two units of OP-1 Putty per patient, but rather approximately 1.3 units of OP-1 Putty per patient. *See* Superseding Indictment, at ¶¶ 48-49.

[5] In *Robison*, the jury convicted both McWane, Inc. and Charles Robison, McWane's vice president of environmental affairs, of knowingly and willfully submitting false statements to the EPA. The trial evidence had shown that, although "Robison had personal knowledge of the problems at [McWane's manufacturing] plant," various plant inspection reports Robison submitted to the EPA on McWane's behalf "showed no problems at the plant." *Id.* at 1228. On appeal, the Eleventh Circuit held that the evidence was nevertheless insufficient to convict Robison of violating 18 U.S.C. § 1001(a)(2) because the government "presented no evidence that Robison ever personally reviewed the plant inspection reports or had personal knowledge of the contents of the plant inspection reports . . . ." *Id.* at 1228-29 ("Certainly, the government introduced evidence that some of the plant inspection reports themselves were false. . . . [But] the government cannot point to any evidence that Robison *actually knew* the contents of the particular *inspection reports* . . . or that Robison *actually knew* that those particular *inspection reports* contained false information."). The court of appeals further held that, insofar as the trial evidence was insufficient to prove beyond a reasonable doubt that Robison knowingly and willfully made a false statement to the EPA, the corporate defendant McWane was necessarily "entitled to a judgment of acquittal." *Id.* at 1229.

Accordingly, even assuming the truth of the Government's factual assertions regarding Philip's "involvement" in the 2007 Annual Report "process," they neither bolster nor provide a sufficient fallback to the Government's legally invalid "collective intent" theory.

III. CONCLUSION

For the reasons set forth above, Count 13 should be dismissed.

Respectfully submitted,

STRYKER BIOTECH , LLC,

/s/ Brien T. O'Connor

Dated: November 16, 2011

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/s/ Brien T. O'Connor
Brien T. O'Connor